HIV Pre-Exposure Prophylaxis (PrEP)
Outline

• NY State HIV Surveillance data
• Ending the Epidemic (EtE)
• What is PrEP?
• Data supporting PrEP
• PrEP guidelines
• Increasing client awareness
• Increasing provider knowledge
• Community Based Organizations
• Additional Resources
Newly Diagnosed HIV Cases, 2006-2015 by Region and Selected Characteristics
Persons Newly Diagnosed with HIV Infection in New York State by Region of Diagnosis, 2006-2015*

*Data as of January 2017
Persons Newly Diagnosed with HIV Infection by Sex Assigned at Birth, NYS, 2006-2015*

*Data as of January 2017
Persons Newly Diagnosed with HIV Infection by Race/Ethnicity, NYS, 2006-2015*

*Data as of January 2017
Persons Newly Diagnosed with HIV Infection by Transmission Risk Group, NYS, 2006-2015*

*Data as of January 2017
Plan to End the AIDS Epidemic

A 3-Point plan announced by the Governor on June 29, 2014

1. Identify all persons with HIV who remain undiagnosed and link them to health care.

2. Link and retain those with HIV in health care, to treat them with anti-HIV therapy to maximize virus suppression so they remain healthy and prevent further transmission.

3. Provide Pre-Exposure Prophylaxis (PrEP) for high risk persons to keep them HIV negative

Reduce the number of new HIV infections to just 750 [from an estimated 3,000] by 2020
PrEP is HIV Prevention

An HIV uninfected person who engages in high risk behavior for HIV takes one pill once a day to prevent becoming infected with HIV.
Common Examples of Pre-Exposure Prophylaxis

- A woman taking birth control pills to prevent pregnancy
- A traveler taking anti-malarial medications when going to an area where there is high likelihood of exposure to malaria
- A person taking antibiotics prior to dental surgery to prevent infection
- A person with HIV taking certain medications to prevent an opportunistic infection
What is PrEP?

- Take one pill once a day (Truvada)
- Regular HIV testing
- Condoms to prevent STDs
- Periodic STD screening
- Education about safer sex practices and options
- Adherence support

Educational and behavioral strategies to reduce HIV and other sexually transmitted infections.
PrEP Trials Have Shown Efficacy in MSM, Heterosexual Men and Women, and IDUs

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population/Setting</th>
<th>Intervention</th>
<th>HIV Infections, n</th>
<th>Reduction in HIV Infection Rate, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEX[1] (N = 2499)</td>
<td>MSM, transgender women, 11 sites in US, South America, Africa, Thailand</td>
<td>TDF/FTC</td>
<td>36</td>
<td>64 (44 (15-63)</td>
</tr>
<tr>
<td>Partners PrEP[2]  (N = 4747)</td>
<td>Serodiscordant couples in Africa</td>
<td>TDF</td>
<td>17</td>
<td>52 (67 (44-81)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TDF/FTC</td>
<td>13</td>
<td>75 (70 (55-87)</td>
</tr>
<tr>
<td>TDF2[3] (N = 1219)</td>
<td>Heterosexual males and females in Botswana</td>
<td>TDF/FTC</td>
<td>9</td>
<td>24 (62 (21-83))</td>
</tr>
<tr>
<td>Thai IDU[4] (N = 2413)</td>
<td>Volunteers from 17 drug Thai treatment centers</td>
<td>TDF</td>
<td>17</td>
<td>33 (49 (10-72))</td>
</tr>
</tbody>
</table>

- 2 additional trials of PrEP (FEM-PrEP[5] and VOICE[6]), both conducted among high-risk African women, did not demonstrate protection against HIV; in both trials, PrEP adherence was very low.

PrEP Works, but Adherence Is Critical

<table>
<thead>
<tr>
<th>Study</th>
<th>Efficacy Overall, %</th>
<th>Blood Samples With TFV Detected, %</th>
<th>Efficacy By Blood Detection of TFV, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx[1]</td>
<td>44</td>
<td>51</td>
<td>92</td>
</tr>
<tr>
<td>iPrEx OLE[2]</td>
<td>49</td>
<td>71</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>75 (TDF/FTC)</td>
<td></td>
<td>90 (TDF/FTC)</td>
</tr>
<tr>
<td>Thai IDU[5]</td>
<td>49</td>
<td>67</td>
<td>74</td>
</tr>
<tr>
<td>VOICE[7]</td>
<td>No efficacy</td>
<td>&lt; 30</td>
<td>NR</td>
</tr>
</tbody>
</table>

IPrEx – Phase 3, Placebo-controlled Study with MSM and Trans-women Who have Sex with Men

<table>
<thead>
<tr>
<th>Received study drug: 1,251</th>
<th>Received placebo: 1,248</th>
</tr>
</thead>
<tbody>
<tr>
<td>36 infections for an overall reduction of 42.3%</td>
<td>64 infections</td>
</tr>
<tr>
<td>50% adherence</td>
<td>50.2% reduction</td>
</tr>
<tr>
<td>90% adherence</td>
<td>72.8% reduction</td>
</tr>
</tbody>
</table>
### Other Important Findings from IPrEx

<table>
<thead>
<tr>
<th>Concern</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients will not tolerate side effects</td>
<td>Medication was well-tolerated</td>
</tr>
<tr>
<td>PrEP will lead to decrease in condom use</td>
<td>Participants actually increased condom use</td>
</tr>
<tr>
<td>PrEP will lead to increase in risk taking</td>
<td>Participants actually decreased their number of sex partners</td>
</tr>
<tr>
<td>PrEP will lead to drug resistance which will complicate treatment</td>
<td>No subsequent drug resistance in those who became infected</td>
</tr>
</tbody>
</table>

- Efficacy was highest (58%) among those at highest risk as measured by self report of unprotected receptive anal intercourse at intake
FDA Approval for PrEP

- Tenofovir [TDF] 300 mg/emtricitabine [FTC] 200 mg (Truvada) [TRV] approved by FDA, July 2012

CDC Guidance

• Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States 2014 – A Clinical Practice Guideline

• Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States 2014 - Clinical Providers Supplement

http://www.cdc.gov/hiv/guidelines/preventing.html
New York State Guidance

Guidance For the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission (1/14/2014)

October 2015 Update

• PrEP Payment Options have been compiled by the New York State Department of Health (see Appendix D). The options include Medicaid, PrEP Assistance Program (PrEP-AP), the Gilead Co-Pay Coupon Card, the Gilead Medication Assistance Program, the Patient Access Network, and most private insurances.

• Updated information about prescribing PrEP for adolescents is provided (see Section II).

• Updated information about managing patients on PrEP who present with a positive HIV screening test or with symptoms suggestive of acute HIV infection is provided (see Section VIII).

www.hivguidelines.org
<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Individuals with Whom PrEP Should Be Discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Men and transgender women who engage in unprotected anal intercourse with men(^1)(^4),(^5),(^6)</td>
<td></td>
</tr>
<tr>
<td>- Women or men attempting to conceive with an HIV-infected partner and women at ongoing risk for acquisition of HIV during pregnancy(^7)</td>
<td></td>
</tr>
<tr>
<td>- Individuals who:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Are in a sexual relationship with a known HIV-infected partner</td>
</tr>
<tr>
<td></td>
<td>- Have multiple or anonymous sexual partners</td>
</tr>
<tr>
<td></td>
<td>- Engage in sexual activity at sex parties or other high-risk venues</td>
</tr>
<tr>
<td></td>
<td>- Are involved in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers and their clients</td>
</tr>
<tr>
<td></td>
<td>- Have been diagnosed with at least one sexually transmitted infection (STI) in the last 12 months(^8),(^9)</td>
</tr>
<tr>
<td></td>
<td>- Report recreational use of mood-altering substances during sex (e.g. alcohol, methamphetamine,(^1)(^4),(^5),(^6),(^7),(^8) cocaine, and ecstasy)</td>
</tr>
<tr>
<td></td>
<td>- Report injecting substances including hormones</td>
</tr>
<tr>
<td></td>
<td>- Are receiving non-occupational post-exposure prophylaxis (nPEP) and demonstrate continued high-risk behavior or have used multiple courses of nPEP(^1)(^0)</td>
</tr>
</tbody>
</table>

\(^{1}\)A 7-item screening index has been developed to identify MSM who are at higher risk of HIV seroconversion (see Appendix A).

\(^{2}\)Ongoing risk for sero-discordant couples during pregnancy includes lack of consistent use of barrier protection, lack of complete viral suppression in the HIV-infected partner for at least 6 months, or both.
New York State Priorities

- Increase client awareness
- Increase clinical provider knowledge
- Increase number of clinicians prescribing PrEP
- Increase access to PrEP and healthcare
- Develop a system that can incorporate future developments
- Research
Increasing Client Awareness

PrEPforSex.org

- Resources for Consumers
- Materials
- Women’s Information Tab
- Videos
  - Beginning the Process
  - Affordability
  - Remembering to take PrEP
  - Condom Use
  - Why PrEP?
  - Side Effects
  - PrEP and Emotions
Increase Clinical Provider Knowledge

**Clinical Education Initiative**
- ceitraining.org
- 20 minute video
- Webinars
- Nametag information card

**CEI Line**
- 1-866-637-2342

**Voluntary Provider Directory**
- To Sign Up
  [https://www.surveymonkey.com/s/S329ZK5](https://www.surveymonkey.com/s/S329ZK5)
- To Access Directory
Increase Clinical Provider Knowledge

PrEP DETAILING

- Targeting 500 providers outside of NYC
- Provide PrEP Detailing Kit
- 175 providers have received PrEP Detailing visits to date
- 125 registered with the NYSDOH PrEP Voluntary Provider Directory
Increase Non-Clinical Provider Knowledge

Education and Training Initiative

Topics
• Role of CBO’s in Promoting Pre-Exposure Prophylaxis for HIV
• Role of Non-clinicians in Promoting PrEP
• HIV Testing in NYS
• Healthy Sex! Linking Gay Men and MSM to Sexual Health Services
• Achieving and Sustaining Viral Suppression Among Women (ETE series – PrEP module)

http://www.hivtrainingny.org/
Relevance to Health Homes/Care Management Agencies

• HIV Infection is a HH qualifying condition.
• Awareness of promotion of efforts to End the Epidemic
• Awareness and promotion of PEP and PrEP services
• Assisting with consumer advocacy and navigation
• Each one of us has an HIV status – Do you know yours?

http://www.hivtrainingny.org/
## Toolkit for Community Based Organizations

### Action Steps for Community Based Organizations

<table>
<thead>
<tr>
<th>At the Organizational Level</th>
<th>At the Programmatic Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Agency leadership and governing board should be well informed about PrEP</td>
<td>✓ Integrate messages about PrEP into all prevention services</td>
</tr>
<tr>
<td>✓ Train your staff about PrEP</td>
<td>✓ Provide community presentations on PrEP</td>
</tr>
<tr>
<td>✓ Highlight PrEP on your agency website</td>
<td>✓ Integrate messages about PrEP into HIV testing services</td>
</tr>
<tr>
<td>✓ Include PrEP in your agency’s social media messaging</td>
<td>✓ As appropriate, link high risk, HIV- clients to providers who prescribe PrEP</td>
</tr>
<tr>
<td>✓ Provide links on key pages of your agency’s website to the NYS PrEP campaign at: <a href="http://www.prepforsex.org">www.prepforsex.org</a></td>
<td>✓ Assist clients with accessing financial assistance for PrEP</td>
</tr>
<tr>
<td>✓ Be familiar with medical providers who prescribe PrEP in your region by reviewing the NYSDOH Voluntary Directory or PrEP/PEP providers at: <a href="http://www.health.ny.gov/diseases/aids/general/prep/">http://www.health.ny.gov/diseases/aids/general/prep/</a></td>
<td>✓ Establish linkage agreements with medical providers to provide their PrEP patients with prevention and supportive services</td>
</tr>
<tr>
<td>✓ Take an active role encouraging medical providers in the region to prescribe PrEP</td>
<td>✓ Partner with CBOs, local health departments and DOH regional offices to link high risk HIV-individuals to PrEP services</td>
</tr>
<tr>
<td>✓ Address community misconceptions about PrEP</td>
<td>✓ Offer support services and/or education for clients on PrEP</td>
</tr>
<tr>
<td>✓ Create an environment where clients can openly consider if PrEP is an option for them</td>
<td></td>
</tr>
</tbody>
</table>
Increase Access to PrEP and Healthcare

Voluntary Provider Directory

- PrEP prescribers are present in areas of the state with the highest risk, thus highest need, of PrEP.
- 350 registered PrEP prescribers (2/22/17)
  - 25% increase compared to October
  - 47 counties (up from 39 counties in October)

To Sign Up
https://www.surveymonkey.com/s/S329ZK5

To Access Directory
Increase Access to PrEP and Healthcare Payment Options

Payment Options for PrEP (Pre-Exposure Prophylaxis)

**Private Insurance**
- Most private insurance covers PrEP.
- Coverage varies by plan. There may be deductibles and co-payments.

**Medicaid**
- [Health Insurance for New York State](https://www.health.ny.gov/diseases/aids/hiv/a36.php?pt=0)
- PrEP prescription costs, medical appointments, and lab tests covered.
- PrEP approved if required and treatment every 3 months.

**PrEP Assistance Program (PrEP-AP)**
- [Gilead](https://www.gilead.com)
- Covers cost of PrEP for individuals who are residents of New York State who are uninsured or underinsured. Financial eligibility is based on 400% of the Federal Poverty Level (FPL).
- Covers costs of doctor's visits and lab testing for uninsured and underinsured individuals.

**Medication Assistance Programs**

<table>
<thead>
<tr>
<th>Program</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilead Co-Pay Coupon Card</td>
<td>- <a href="https://www.gilead.com">Gilead</a></td>
</tr>
<tr>
<td></td>
<td>- Covers up to 100% of costs in prescription to payers.</td>
</tr>
<tr>
<td></td>
<td>- Patients must have insurance.</td>
</tr>
<tr>
<td></td>
<td>- Patients must be enrolled in Medicare or Medicaid.</td>
</tr>
<tr>
<td></td>
<td>- No income eligibility requirements.</td>
</tr>
<tr>
<td></td>
<td>- Not available for patients under 18 years of age.</td>
</tr>
<tr>
<td>Gilead Truvada for PrEP Medication Assistance Program</td>
<td>- <a href="https://www.gilead.com/truvada.com">Gilead</a></td>
</tr>
<tr>
<td></td>
<td>- Covers prescription costs.</td>
</tr>
<tr>
<td></td>
<td>- Patients must have uninsured or partial insurance does not cover any prescription costs.</td>
</tr>
<tr>
<td></td>
<td>- Not available for patients under 18 years of age.</td>
</tr>
</tbody>
</table>

New York State Department of Health, AIDS Institute - Updated April 2018
Increase Access to PrEP and Healthcare Models of Care

- PrEP Specialist
- Local Health Department STD Clinic
- Syringe Exchange Programs
- Planned Parenthood
- Telemedicine
Increasing PrEP Use

A focused effort by New York State to increase PrEP uptake started in June 2014 and included:

1. Provider Training
2. Raising Awareness
3. Ensuring Medicaid Coverage

Number of New York State Medicaid beneficiaries receiving PrEP.

SOURCE: NYS Medicaid Data Warehouse (based on Medicaid data loaded through July 2015).
New York State and PrEP

✓ At the 2016 21st International AIDS Conference in Durban, South Africa Keith Rawlings, MD presented data on the number of people in the US on PrEP.

✓ We’re proud to say that New York State had the most people on PrEP per capita.